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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,423	06/28/2001	Ronald H. Chiarello	SYNGEN-06067	6875

23535 7590 02/13/2006

MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
SUITE 350  
SAN FRANCISCO, CA 94105

EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/894,423	<b>Applicant(s)</b> CHIARELLO ET AL.	
	<b>Examiner</b> Celine X. Qian Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 6/28/01, 4/7/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1 and 4 are pending in the application.

This Office Action is in response to the Amendment filed on 1/3/06.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/3/06 has been entered.

#### ***Response to Amendment***

The rejection of claims 1 and 4 under 35 U.S.C. 102 has been withdrawn in light of Applicant's amendment.

The rejection of claims 1 and 4 under 35 U.S.C. 112 1<sup>st</sup> paragraph has been withdrawn in light of Applicant's amendment.

Claims 1 and 4 are rejected under 35 U.S.C. 103 (a) for reasons discussed below.

#### ***New Grounds of Rejection Necessitated by Amendment***

##### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snitman, in view of Vinayak et al (for same reasons as set forth of the record mailed on 9/30/02 and 6/17/03).

Snitman teaches reacting an oligonucleotide bound at its 3' end to a solid support with the linker  $[(CH_3)_2CH]_2NP(OCH_3)O(CH_2)_8NH(DMT)$  wherein DMT is a dimethoxytrityl group, to form a 5' amine functionalized oligonucleotide. This is then reacted with fluorescein isothiocyanate. In the process of reacting this with the fluorescein isothiocyanate, the protected amine group loses its protective DMT group. (See entire document, especially col.3, line 17-col. 4, line 16 and col.8, line 67-col.9, line 6). However, Snitman does not teach a linker that is identical to the linkers recited in the claims. Specifically, the moiety on the phosphate oxygen is a methyl group and not  $CH_2CH_2CHN$ .

Vinayak et al. teach labeling an oligonucleotide bound at its 3' end to a polystyrene support by reacting the oligonucleotide with an amino-linker phosphoramidite reagent. The protected amino group is detritylated (thus deprotected) then reacted with an activate label, such as TAMRA- $CO_2H$ . Other labels taught for use in the methods include: 6-FAM, rhodamines and fluoresceins. (See entire document, especially col. 5, lines 46-63, col. 11, lines 16-58, cols. 13-16, col.19, Example 3, col. 20, Example 5 and col.22, Example 9). Absent evidence from the contrary it is assumed that the amino-linker phosphoramidite reagent is the same as shown in col.11, lines 30-40 except having DMT rather than MMT as the protecting group. This assumption is grounded in the knowledge that commercially-available DNA synthesis reagents typically employ DMT, that both groups are acid labile protecting groups and also in the

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summary of the steps of a synthesis cycle taught by Vinayak et al. in col. 10 lines 46-col. 11, line 15.

It would have been obvious to one of ordinary skill in the art to combined teaching of both Snitman and Vinayak and reach the method of labeling oligonucleotides using the claimed bifunctional linker. The ordinary artisan would have been motivated to do so because using any moiety at that position that could undergo beta-elimination would have worked for the method taught by Snitman. As such, the methyl is an equivalent of the  $\text{CH}_2\text{CH}_2\text{CHN}$ . Absent evidence from the contrary, one of ordinary skilled in the art would have reasonable expectation of success to use  $\text{CH}_2\text{CH}_2\text{CHN}$  instead of methyl group for the bifunctional linker. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

**CELIAN QIAN**  
**PATENT EXAMINER**

